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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,576	06/02/2006	Mi Rim Jin	DI-011	6982
38051	7590	06/01/2007		
KIRK HAHN 14431 HOLT AVE SANTA ANA, CA 92705			EXAMINER BETTON, TIMOTHY E	
			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			06/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,576	Applicant(s) JIN ET AL.	
	Examiner Timothy E. Betton	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3 sheets</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections –35 USC§ 112- 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some conditions of obesity, does not reasonably provide enablement for other conditions of obesity and disease states thereof . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As stated in MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. In re Wands, set forth the following eight factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC§ 112, 1st Paragraph:

1. The nature of the invention
2. The state of the prior art
3. The predictability or lack thereof in the art
4. The amount of direction or guidance present

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5. The presence or absence of working examples
6. The breadth of the claims
7. The quantity of experimentation needed
8. The level of skill in the art

The state of the prior art

The state of the prior art in regard to subject invention is still within the research stages.

The predictability or lack thereof in the art

The unpredictability in the art is significant because of the various etiologies, which result in obesity. There are two factors, which suggest lack of predictability for this instant invention.

Firstly, the terminology of "preventing" the elected disease state, type II diabetes is not enabling. There is nothing in the specification or instant claims, which suggest that instant invention prevents type II diabetes. There is evidence of more than one gene locus in the causation of noninsulin-dependent diabetes mellitus (NIDDM) coupled with the mutagenicity of the diabetic gene (McKusick, V., John Hopkins University, Online Mendelian Inheritance in Man, #125853 Diabetes Mellitus, Non-Insulin Dependent; NIDDM, (1993) printed pages 1-19, especially page 1).

Secondly, certain disease states manifest susceptibilities that would not effectively respond to a dehydroniciferyl formulation regimen. For example, the

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complex nature of type II diabetes presents such susceptibilities due to the diseases stage of development and the variables factors (i.e., bioavailability, lack of therapeutic effect, other underlying physiological factors) of patient with said disease.

Consequently, there would be undue experimentation due to such unpredictability.

The amount of direction or guidance present

The amount of direction or guidance present is deficient within the instant claims. The instant specification, extrapolates on certain embodiments of adaptation. Proper determination is uncertain because of critical methods, processes, or steps that are not so apparent, therefore making proper direction and guidance uncertain.

Due to the nature of the invention, skilled direction and guidance should be evident and of such sufficient comprehensibility that one of said skill could at once interpret the embodiments facilitated by such direction and guidance. In instant invention, the amount of sufficient direction and guidance is lacking.

There is no amount of direction or guidance disclosed within instant specification or claims to suggest that instant invention prevents the complex disease state of type II diabetes.

The presence or absence of working examples

There is absence of working examples as to how said agent is enabled to prevent obesity disorders such as steatosis, hyperlipidemia, and cardiovascular disease.

The quantity of experimentation needed

The quantity of experimentation needed is substantial. As disclosed within the instant specification (pages 11-14), there presents a multiplicity of factors in regard to disclosed agents used in said formulation. Among other considerations, bioavailability is a central factor that varies from individual to individual manifesting with such conditions in need of said treatment. Many types of extensive and laborious experimentation are routine or common in the art. However, disclosures in the specification and claim set are inconclusive, therefore more experimentation is required.

The level of skill in the art

The level of skill in the art is reasonably substantial with necessary on going research required.

Again, as stated above in MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. As a result of the explanation disclosed above, the enablement requirement is not adequately satisfied in reference to the scope of the alleged invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

TEB